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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.        | CONFIRMATION NO. |
|--|-------------|----------------------|----------------------------|------------------|
| 10/047,079   | 01/14/2002  | Meir Rosenberg       | 022719-0026                | 5373             |
| 21125  | 7590        | 03/29/2004           |                            |                  |
| NUTTER MCCLENNEN & FISH LLP<br>WORLD TRADE CENTER WEST<br>155 SEAPORT BOULEVARD<br>BOSTON, MA 02210-2604 |             |                      | EXAMINER<br>DEAK, LESLIE R |                  |
|  |             |                      | ART UNIT                   | PAPER NUMBER     |
|  |             |                      | 3762                       | 3                |

DATE MAILED: 03/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/047,079

Applicant(s)

ROSENBERG ET AL.

Examiner

Leslie R. Deak

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 1.2.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 8-10, and 14-18 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,141,502 to Macaluso, Jr. Macaluso discloses a catheter with a proximal and distal end an inner lumen that extends between the proximal and distal ends (see FIG 7, 9). The distal end may comprise a coil-shaped region with between one and ten coils, between one and forty fluid entry ports thereupon, and a distal fluid port. The catheter is comprised of two sections: a distal tube body 19 and a bladder coil 23 that are connected at hub 27, wherein the tube portions are formed of polymeric material that retains its shape in a coiled position (see FIG 7, column 2, lines 1-5). With regard to the claim limitations drawn to the method of forming the catheter, the method of forming the device is not germane to the issue of patentability of the device itself. Therefore, this limitation has not been given patentable weight.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 2-7 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,141,502 to Macaluso, Jr. in view of US 6,595,966 to Davey et al. Macaluso discloses the apparatus as claimed with the exception of the shaped inlet ports, increasing diameter, and size limitations claimed by applicant. Davey discloses a catheter that utilizes a tapered shape that increases the diameter of the inner lumen from the distal end to the proximal end in order to maximize flow rate and reduce trauma to the fluid flowing therein (see columns 1-2). Davey further discloses that the principles of the tapered design of his catheter may be applied to a catheter design that is dimensioned according to the needs of its specific use (see column 8, lines 9-14). Furthermore, absent an indication as to the criticality of the claimed dimensions of the catheter and shapes and sizes of the inlet openings, it is considered an obvious matter of design choice, since applicant has not disclosed that the specific dimensions and shapes solve any stated problem or is for any particular purpose and it appears that the invention would perform equally well with generically suitable diameters, lengths, and inlet port shapes. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to provide the catheter disclosed by Macaluso with a tapered internal diameter and create the Macaluso catheter of an appropriate size for the desired operation in order to increase fluid flow through the catheter and provide an appropriately-dimensioned catheter, as taught by Davey.

**Conclusion**

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure

- a. US 6,620,202 Bottcher et al
  - i. Stent and catheter with variably coiled distal end
- b. US 6,676,623 Whitmore, III
  - ii. Drainage catheter with increasing inner diameter

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 703-305-0200. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lrd  
19 March 2004

*Patricia Bianco* 3/20/04  
*Patricia Bianco*  
*Primary Examiner*